

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: March 29, 2016

SUBJECT: Dicamba. Acute and Chronic Dietary Exposure Assessments of Food and Drinking

Water to Support the Use of Dicamba on Dicamba-Tolerant Cotton and Soybean for Amended Section 3 Registration, and Registration of the New N,N-Bis-(3-aminopropyl)

methylamine (BAPMA) Salt Formulation.

PC Code: 029801, 029802, 029806, 128931, 128944 & 129043	DP Barcode D410346, D429869, D429962 & D429963
Decision No.: 432752, 463710, 467977	Registration No.: 524-582 & 7969-GUL
Petition No.: 2F8067 & 0F7725	Regulatory Action: Amended Section 3 Registrations & R170 New Food-Use Registrations
Risk Assessment Type: Single Chemical, Dietary	Case No.: 0065
TXR No.: NA	CAS No.: 1918-00-9
MRID No.: None	40 CFR: §180.227

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Executive Summary

Acute and chronic aggregate dietary food and drinking water exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity

Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). These analyses were conducted in support of a human health risk assessment for the amended Section 3 uses of dicamba on dicamba-tolerant cotton and soybeans proposed by Monsanto. It will also be used to support the requested new use registration of the Engenia herbicide, a N,N-Bis-(3-aminopropyl) methylamine (BAPMA) salt formulation of dicamba developed by BASF. This memorandum was reviewed by two peer reviewers of the DESAC as per the current DESAC SOP.

Attached are the acute and chronic aggregate dietary risk assessments made to support all of the newly proposed registrations requested for dicamba, as well as its existing uses. These dietary risk assessments included all the residues of concern for dicamba risk assessment which include dicamba, and depending in the matrix, one or more of the following metabolites expressed as parent equivalents; 5-OH dicamba, 3,6-dichloro-2-hydroxybenzoic acid (DCSA), and 2,5-dichloro-3,6- dihydroxybenzoic acid (DCGA) metabolites, expressed as parent dicamba equivalents. Tolerance-level residues, DEEM-FCIDTM (ver. 7.81) default processing factors, as well as 100 percent crop treated (%CT) data for the acute determination along with average residues from field trial studies for crops and %CT refinements for the chronic analysis were used. Modeling estimates for ground water (PRZM-GW) were used to estimate residue concentrations in drinking water for both the acute and chronic assessments.

Acute Dietary Exposure Assessment

The acute analysis was an unrefined determination which used tolerance levels and 100 %CT for all existing and proposed uses. The population subgroup of females 13-49 years was concluded not to have a toxicological endpoint for dietary risk assessment. The dietary exposure analyses that were performed result in acute dietary risk estimates that are below the Agency's level of concern for both food and water. For the U.S. population the exposure was 0.042760 mg/kg/day, which utilized 15% of the acute population adjusted dose (aPAD) at the 95th percentile. The highest exposure and risk estimates were for all infants. At the 95th percentile, the exposure for all infants was 0.088733 mg/kg/day, which utilized 31% of the aPAD.

Chronic Dietary Exposure Assessment

The chronic analysis was a refined determination which used average residues based on field trial studies for crops, tolerance levels for livestock commodities, and relevant %CT data for several existing uses. The chronic risk estimates for dicamba are below the Agency's level of concern for the general U.S. population and all population subgroups. The most highly exposed population subgroup is children ages 1-2 with a risk estimate for dicamba for food and water of 42% of the cPAD.

Cancer Dietary Exposure Assessment

Dicamba is classified as not likely to be carcinogenic to humans; therefore, a cancer dietary assessment was not performed.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose that HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References that discuss the acute and chronic risk assessments in more

detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6 (20-AUG-1999).

The most recent dietary exposure analysis was conducted in support of the Section 3 registration of dicamba on sweet corn (D347355, S. J. Levy, 01/16/2008).

II. Residue Information

Monsanto has submitted petitions PP#2F8067 and PP#0F7725 requesting Section 3 registration for the amended use of dicamba on dicamba-tolerant cotton and soybeans, respectively. In addition, BASF has also requested registration of its Engenia herbicide, a new N,N-Bis-(3-aminopropyl) methylamine (BAPMA) salt formulation of dicamba on conventional crops, as well as on dicamba-tolerant cotton and soybeans. Dicamba is registered for pre-plant application on conventional crops but not for post-emergence treatment because injury could occur if it were to come in contact with the roots, stems, or foliage of these plants. To enable post-emergence application, Monsanto has developed a dicamba-tolerant variety of cotton and soybean capable of receiving treatment up to seven days before harvest.

Dicamba is a selective benzoic acid herbicide registered for controlling a wide variety of broadleaf weeds and woody plants prior to their emergence. Dicamba is available in a number of forms with registered uses maintained on a wide variety of crop and livestock commodities. Permanent tolerances are established under 40 CFR §180.227(a)(1) for dicamba and its 3,6-dichloro-5-hydroxybenzoic acid (5-OH dicamba) metabolite. Additional tolerances are established under 40 CFR §180.227(a)(2) for dicamba and its 3,6-dichloro-2-hydroxybenzoic acid (also known as 3,6-diclorosalicyclic acid or DCSA) metabolite, as well as under 40 CFR §180.227(a)(3) for dicamba, 5-OH dicamba, and the DCSA metabolite. HED has recommended for the following tolerances on the human foods of the subject commodities which calls for the cotton tolerance to be increased from 0.2 to 0.3 ppm and the soybean tolerance to remain at 10.0 ppm based on the residue data submitted.

Cotton, undelinted seed	3.0 ppm
Sovbean, seed	10.0 ppm

In consultation with the HED Residues of Concern Knowledgebase Subcommittee (ROCKS) cochairs on March 18, 2013, the residues of concern were determined for both tolerance setting and risk assessment purposes (D410934, A. Kamel, 06/03/2013). Newly submitted metabolism studies for dicamba-tolerant cotton and soybean supports including parent, 5-OH dicamba, as well as the DCSA metabolite as the residues of concern for tolerance expression in these crops. For risk assessment, the residues of concern in cotton will be those which are being established for tolerance expression. However, soybean will include parent, 5-OH dicamba, DCSA, as well as the DCGA metabolite for risk assessment. The residues of concern for dicamba are summarized below in Table 1.

Table 1. Dicamba Residues of Concern.			
Matrix	Tolerance Expression	Residues for Risk Assessment	
Barley, corn, grasses, oats, proso millet, sorghum, sugarcane, and wheat	Dicamba + 5-OH dicamba	Dicamba + 5-OH dicamba	
Asparagus	Dicamba + DCSA ¹	Dicamba + DCSA	
Cotton	Dicamba + 5-OH dicamba + DCSA	Dicamba + 5-OH dicamba + DCSA	
Soybeans, and aspirated grain fractions (AGFs)	Dicamba + 5-OH dicamba + DCSA	Dicamba + 5-OH dicamba + DCSA + DCGA ²	
Livestock	Dicamba + DCSA	Dicamba + DCSA	
Drinking Water	NA ³	Dicamba + DCSA	

DCSA also referred to as 3,6-dichloro-2-hydroxybenzoic acid or as 3,6-dichlorosalicylic acid.

Residue Data used for Acute and Chronic Assessments:

For the acute assessment, tolerance-level residues, 100% CT data, and DEEM-FCID™ (ver. 7.81) default processing factors were used. The chronic analysis did require refinement so average residue values were used for crops, as well as relevant %CT data. Monsanto has submitted adequate crop field trial data to support the registration of the requested amended uses of dicamba on dicamba-tolerant cotton (D408384, P. Savoia, 03/29/2016) and soybeans (D384422, A. Kamel, 04/17/2013). In regard to the registration of the new BAPMA salt formulation, BASF has submitted adequate bridging data for demonstrating product equivalency (D402514 & D421306, P. Savoia, 03/29/2016). The tolerance limits established for dicamba are presented below along with corresponding average residue values derived from the supporting field trials studies. It is important to note that translated field trial residue data were used for a few of the cereal grains (millet, oat, rye, and teff).

180.227 Dicamba; tolerances for residues.

(a) General. (1) Tolerances are established for the residues of the herbicide dicamba (3,6-dichloro-o-anisic acid), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the sum of the residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite, 3,6-dichloro-5-hydroxy-o-anisic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

Commodity	Tolerance (ppm)	Average Residue (ppm) ¹
Barley, grain	6.0	1.3
Corn, field, grain	0.1	0.01
Corn, pop, grain ²	0.1	0.01
Corn, sweet, kernel plus cob with husks removed	0.04	0.02
Millet, proso, grain ³	2.0	0.4
Oat, grain ³	2.0	0.4
Rye, grain ³	2.0	0.4
Sorghum, grain, grain	4.0	1.5
Sugarcane, cane	0.3	0.14
Sugarcane, molasses	5.0	3.4

² DCGA is also referred to as 2,5-dichloro-3,6- dihydroxybenzoic acid.

³ NA – Not Applicable.

Commodity	Tolerance (ppm)	Average Residue (ppm) ¹
Teff, grain ⁴	6.0	1.3
Wheat, grain	2.0	0.4

¹ Residue Values are based on the field trial datasets used for tolerance reassessment as cited in the Residue Chemistry Chapter made in support of the 2005 RED (D317699, C. Olinger, 12/20/2005).

(2) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-o-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite, 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

Commodity	Tolerance (ppm)	Average Residue (ppm) ¹
Asparagus	4.0	1.0
Cattle, fat	0.3	ND^2
Cattle, kidney	25.0	ND
Cattle, meat	0.25	ND
Cattle, meat byproducts, except kidney	3.0	ND
Goat, fat	0.3	ND
Goat, kidney	25.0	ND
Goat, meat	0.25	ND
Goat, meat byproducts, except kidney	3.0	ND
Hog, fat	0.3	ND
Hog, kidney	25.0	ND
Hog, meat	0.25	ND
Hog, meat byproducts, except kidney	3.0	ND
Horse, fat	0.3	ND
Horse, kidney	25.0	ND
Horse, fat	0.05	ND
Horse, meat	0.25	ND
Horse, meat byproducts, except kidney	3.0	ND
Milk	0.2	ND
Sheep, fat	0.3	ND
Sheep, kidney	25.0	ND
Sheep, meat	0.25	ND
Sheep, meat byproducts, except kidney	3.0	ND

¹ Residue Values are based on the field trial datasets used for tolerance reassessment as cited in the Residue Chemistry Chapter made in support of the 2005 RED (D317699, C. Olinger, 12/20/2005).

(3) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-o-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolites, 3,6-dichloro-5-hydroxy-o-anisic acid, and 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

² Field corn data are used for translation.

³ Wheat data are used for translation.

⁴ Barley data are used for translation.

² ND – Not Determined.

Commodity	Tolerance (ppm)	Average Residue (ppm)
Soybean, seed	10.0	$1.1^{1,2}$
Cotton, undelinted seed ³	3.0	0.54

¹ Residue Values are based on the field trial datasets made on conventional soybeans used for tolerance reassessment as cited in the Residue Chemistry Chapter made in support of the 2005 RED (D317699, C. Olinger, 12/20/2005).

Fish: To determine whether or not residues are present in fish, HED now routinely checks USDA Pesticide Data Program (PDP) monitoring data regardless of the pesticide's uses and physicochemical properties. For this assessment, a search of the USDA PDP database found that there were no samples of catfish analyzed for the residues of dicamba from 2008 through 2010, and no samples were analyzed for salmon in 2013. As a result, residues in fish were not included in this dietary exposure and risk assessment.

III. Percent Crop Treated Information

For the existing uses attributed to dicamba, BEAD provided a compilation of percent crop treated (%CT) data presented in Attachment 1 to aid in the refinement of the chronic dietary risk assessment (D427534, J. Alsadek, 06/25/2015). The following average percent crop treated estimates were used in the chronic dietary risk assessment for the following crops that are currently registered for dicamba: asparagus: 5%; barley: 5%; corn: 10%; oats: 2.5%; sorghum: 15%; sugarcane: 20%; sweet corn: 1%; and wheat: 10%. One hundred percent crop treated was assumed for all other applicable crops (100 %CT).

IV. Drinking Water Data

The Environmental Fate and Effects Division (EFED) provided the Attachment 2 updated drinking water estimates for use in this dietary risk assessment (D404824, R. Baris, 03/28/2013). This assessment remains current since no new fate data have been submitted and it was derived with the latest models used by EFED for estimating pesticide residues in drinking water (personal communication, M. Corbin, 08/19/2015). For this determination, EFED conducted a Tier I PRZM GW drinking water assessment from groundwater sources for the proposed new uses. Residues of concern for drinking water for risk assessment purposes were the parent and its DCSA metabolite. Table 2 provides the modeling estimates for drinking water summarized from surface water and ground water sources. For the purposes of this assessment, the highest (most conservative) PRZM-GW values were used for the acute (329 ppb parent + 0.041 ppb DCSA) and chronic (187 ppb parent + 0.041 ppb DCSA) assessments. The combined estimated drinking water residues for peak concentration (used in the acute assessment) and chronic were 329 and 187 ug/L (ppb), respectively. The model and its description are available at the EPA internet site: http://www.epa.gov/oppefed1/models/water/.

Table 2. DICAMBA (parent only) Preliminary Cotton Runs for Dicamba (PCA corrected – 0.87)

Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average
				(ug/L)
SW	CAcotton_wirrgSTD.txt	7.72	6.62	1.07
(PRZM/EXAMS)	MScottonSTD.txt	53.37	44.5	6.52
	NCcottonSTD.txt	32.14	27.32	4.24

² The field trial data acquired for dicamba-tolerant soybeans which include the additional DCGA required for risk assessment yield total residue concentrations which are 10-fold lower on average and are not used for assessment since the conventional crop data provide a more conservative estimation (D384422, A. Kamel, 04/17/2013).

Recommended tolerance level (D408384, P. Savoia, 03/29/2016).

⁴ Residue Values are based on the field trial datasets used for tolerance establishment requested in the current petition (D408384, P. Savoia, 03/29/2016).

Table 2. DICAMBA (parent only) Preliminary Cotton Runs for Dicamba (PCA corrected – 0.87)

Groundwater		Peak	Post breakthrough average	30-year average
PRZM-GW	GAcoastal	41.9	28.2	24.9
(no pca applied)	DELMARVA	192	121	117
	FLCitrus	238	161	155
	FLPotato	56.8	19.2	18.1
	NCcoastal	65.3	32.6	29.3
	WIsands	329	187	158
SCIGROW		0.0015		

Note: the highest estimates are in bold.

Table 3. DCSA (PCA corrected – 0.87)

Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average (ug/L)
SW (PRZM/EXAMS)	MScottonSTD.txt	2.97	2.59	0.63
Groundwater		Peak	Post breakthrough average	30-year average
PRZM-GW	GAcoastal*	4.47E-5	3.93E-5	2.38E-5
(no pca applied)	DELMARVA	1.94E-4	1.65E-4	4.45E-5
	FLCitrus	0.041	0.041	0.018
	FLPotato*	5.71E-11	3.67E-11	3.114E-11
	NCcoastal	7.31E-5	3.64E-5	2.59E-5
	WIsands*	8.3E-4	7.66e-4	3.67E-4
SCIGROW		0.0059		

*100 year simulation

Note: the highest estimates are in bold.

In regard to the registration of the new Engenia herbicide, the BAPMA counter ion is known to have greater toxicity than the dicamba active ingredient. Because it is not possible to delineate exposure between the dicamba and BAPMA portion of the molecule when this end-use product is applied, drinking water estimates must be adequately protective. To ensure the dicamba drinking water estimates are protective, EFED has examined drinking water exposures for dicamba versus the BAPMA counter ion (personal communication, W. Eckel, 07/15/2015). EFED used the Mississippi (MS) cotton scenario, a benchmark high-runoff scenario, to compare exposures from applications of the BAPMA end-use product. This modeling found the 365-day average concentrations for dicamba-acid and BAPMA were comparable at 11 ppb and 11.8 ppb, respectively, for the Index Reservoir. The drinking water estimates provided are considered to be protective since the lowest adverse effect doses were selected for assessment.

V. DEEM-FCIDTM Program and Consumption Information

The dicamba acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID, Version 3.16, which incorporates 2003-2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two nonconsecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. However, for acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 2003-2008 WWEIA consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12,

youth 13-19, adults 20-49, females 13-49, and adults 50-99 years old.

For a chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For an acute exposure assessment, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

VI. Toxicological Information

The Risk Assessment Branch (RAB) V/VII toxicologists have re-evaluated the dicamba database and have updated the endpoints as necessary for this assessment. For this action there are several compounds to consider which include dicamba acid, the dicamba metabolites (DCSA, 5-OH dicamba, and DCGA), and the dicamba BAPMA counter ion. The toxicological database is sufficient for assessing the toxicity of and characterizing the hazards of dicamba. Separate assessments of dicamba acid, the dicamba metabolites (DCSA, 5-OH dicamba, and DCGA), and the dicamba BAPMA counter ion were not needed because the lowest adverse effect doses were selected for assessment. The toxicological doses and endpoints for dicamba for use in the dietary assessment are summarized in Table 4.

Table 4. Summary of Toxicological Doses and Endpoints for Dicamba Used for Dietary Exposure Assessment.			
Exposure Scenario	Point of Departure	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children	NOAEL = 29 mg/kg/day Acute RfD = 0.29 mg/kg/day	$UF_{A}=10x$ $UF_{H}=10x$ $FQPA SF = 1X$ $aPAD = \underbrace{acute \ RfD}_{FQPA \ SF}$ $= 0.29 \ mg/kg/day$	Dicamba BAPMA Rat Developmental Study Maternal NOAEL is 29 mg/kg/day in dams (20 as acid form). LOAEL is 86 mg/kg/day in dams, based on ataxia, unsteady gait and convulsions (60 as acid form). Developmental NOAEL.288 mg/kg/day (200 as acid equivalent).
Acute Dietary (Females 13-49 years of age)	N/A	N/A	No developmental toxicity attributed to acute exposure

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	Table 4. Summary of Toxicological Doses and Endpoints for Dicamba Used for Dietary Exposure Assessment.			
Exposure Scenario	Point of Departure	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects	
Chronic Dietary (All populations)	Offspring NOAEL= 4 mg/kg/day Chronic RfD = 0.04 mg/kg/day	$UF_{A}=10x$ $UF_{H}=10x$ $FQPA SF = 1X$ $cPAD = \underline{chronic RfD}$ $FQPA SF$ $= 0.04 \text{ mg/kg/day}$	Reproductive study in rats with DCSA metabolite. Offspring LOAEL = 37 mg/kg/day based on decreased pup weights in F1 generation on PND 14 and 21 (both sexes) and PND 18 (females).	
Cancer (Oral, dermal, inhalation)	Dicamba is classified as no	t likely to be carcinogenic to l	humans.	

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

VII. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The following summarizes the DEEM-FCID (ver. 3.16) chronic exposure analyses. Acute and chronic aggregate (food + water) analyses were performed using DEEM-FCID estimating the dietary exposure of the U.S. population and various population subgroups. The results are summarized in Table 5. The resulting acute food and water risk estimates were less than HED's level of concern (<100% aPAD) for the general U.S. population and all population sub-groups; All infants < 1 year old had the highest acute dietary risk at 31% of the aPAD. The resulting chronic food and water exposure estimates were less than HED's level of concern (<100% cPAD) for the general U.S. population and all population sub-groups; children 1-2 years old had the highest dietary risk at 42% of the cPAD.

Table 5. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Dicamba.						
D 1.: 0.1	Acute I (95 th Per		Chronic Dietary ²			
Population Subgroup	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD		
General U.S. Population	0.042760	15	0.006319	16		
All Infants (< 1 year old)	0.088733	31	0.014024	35		
Children 1-2 years old	0.075295	26	0.016988	42		
Children 3-5 years old	0.065788	23	0.011948	30		
Children 6-12 years old	0.047142	16	0.007618	19		
Youth 13-19 years old	0.032166	11	0.004936	12		
Adults 20-49 years old	0.035172	12	0.005526	14		
Adults 50-99 years old	0.029776	10	0.005340	13		
Females 13-49 years old	N/A³	N/A	0.005465	14		

Acute dietary analysis derived from a 0.29 mg/kg/day aPAD for the general population.

VIII. Characterization of Inputs/Outputs

HED has conducted a highly conservative, health protective assessment for the requested amended use of dicamba on dicamba-tolerant cotton and soybean. Tolerance level residues for all commodities along with 100% CT were used in the acute dietary exposure assessments. A refined chronic dietary exposure assessment was performed which used average residues from field trial studies for crops, tolerance levels for livestock commodities, and relevant %CT data. A critical commodity contribution analysis was conducted for the most highly exposed population subgroup, children 1-2 years of age. This analysis shows that water and milk are the dietary risk drivers of dicamba comprising approximately 35%, and 21% of the total chronic exposure, respectively. The use of anticipated residues, empirical processing factors, and additional %CT data would refine further HED's exposure and risk estimates for dicamba.

IX. Conclusions

Unrefined acute and refined chronic aggregate (food + water) dietary risk assessments were conducted for dicamba using DEEM-FCID (ver. 3.16) modeling. The acute assessment used tolerance-level residues, 100% CT data, and DEEM-FCID™ (ver. 7.81) default processing factors for analysis. The chronic analysis did require refinement so average residue values from field trial studies were used for crops as well as relevant %CT data. The resulting acute aggregate risk estimate was less than HED's level of concern. For the general U.S. population and all population subgroups in the acute analysis all dietary risk estimates were ≤31% aPAD. The resulting chronic aggregate exposure estimate was less than HED's level of concern. For the general U.S. population, the cPAD was 16% while the most highly-exposed population subgroup in the chronic analysis was Children 1-2 years old (42% cPAD).

² Chronic dietary analysis derived from a 0.04 mg/kg/day cPAD for the general population.

³ N/A – not applicable, no endpoint was concluded for this population subgroup.

⁴ Highest exposures found for each assessment are noted in bold.

References

DP No.: D347355

Subject: **Dicamba:** Acute and Chronic Aggregate Dietary (Food and Drinking Water)

Exposure and Risk Assessments for the Proposed Section 3 Registration Action on

Sweet Corn.

From: S. J. Levy

To: M. Clock-Rust and D. Rosenblatt

Dated: 01/16/2008

MRID No.: None

DP No.: D410934

Subject: Residues of Concern in Dicamba Tolerant Crops.

From: A. Kamel
To: M. Walsh
Dated: 06/13/2013

MRID No.: None

DP No.: D408384

Subject: **Dicamba.** Section 3 Registration for the Amended Use of Dicamba on Dicamba-

Tolerant Cotton. Summary of Analytical Chemistry and Residue Data.

From: P. Savoia

To: W. Irwin, K. Montague, and M. Walsh

Dated: 03/29/2016

MRID No.: 48728701-48728704

DP No.: D384422

Subject: **Dicamba**. New Use of Dicamba on Dicamba-Tolerant Soybean. Petition for

Establishment of New Tolerances for Soybean Forage and Soybean Hay. Residue

Chemistry Summary.

From: A. Kamel

To: K. Montague, and M. Walsh

Dated: 04/17/2013

MRID No.: 47899501, 47899523, & 47899524

DP No.: D402514 & D421306

Subject: **Dicamba.** Bridging Data Demonstrating DGA (diglycolamine), BAPMA (N,N-Bis-

(3-aminopropyl) methylamine) and DETA (diethylenetriamine) Salt Product Equivalency, and the Independent Laboratory Validation of the BASF Method Developed for Determining Dicamba Residues in Crops. Abbreviated Residue

Chemistry Review.

From: P. Savoia

To: W. Irwin, K. Montague, and M. Walsh

Dated: 03/29/2016

MRID No.: 49379301-49379305

_

DP No.: D427534

Subject: Updated Screening Level Usage Analysis (SLUA) Report for Dicamba Case, PC #

(029801, 029802, 029803, 029806, 128931, 129043, and 128944), DP # 427534.

From: J. Alsadek
To: K. Montague
Dated: 06/25/2015

MRID No.: None

DP No.: D404824

Subject: Drinking Water Exposure Assessment for the Section 3 New Use of Dicamba

Diglycolamine Salt (DGA) and its Degradate 3,6-dichlorosalicylic acid (DCSA)

on Dicamba-Tolerant Cotton.

From: R. Baris
To: M. Walsh
Dated: 03/28/2013
MRID No.: None

X. List of Attachments

1. Attachment 1: BEAD Memo on Projected Percent Crop Treated Estimates for Dicamba.

- 2. Attachment 2: EFED Memo on the Estimation of Drinking Water Residues.
- 3. Attachment 3: Acute Residue Data File of Inputs.
- 4. Attachment 4: Acute Dietary Assessment Results File.
- 5. Attachment 5: Chronic Residue Data File of Inputs.
- 6. Attachment 6: Chronic Dietary Assessment Results File.
- 7. Attachment 7: Critical Commodity Contribution Analysis for Children 1-2 yrs.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460



JUN.252015

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Updated Screening Level Usage Analysis (SLUA) Report for Dicamba Case, PC #

(029801, 029802, 029803, 029806, 128931, 129043, and 128944), DP # (427534)

FROM: THRU:

Jihad Alsadek, Ph.D., Economist

A Science and Information Analysis Branch

Diann Sims, Chief Science Information and Analysis Branch Biological and Economic Analysis Division (7503P)

TO: Kathryn Montague, Risk Manager

Herbicide Branch

Registration Division (7505P)

This memorandum transmits an updated Screening Level Usage Analysis (SLUA) report for the dicamba case (previously completed in 2012). The usage data in the updated SLUA (2015) are an amalgamation of USDA/NASS and Private Pesticide Market Research data from 2004 to 2013.

The current SLUA shows an increase in usage, in pounds a.i. and percent crop treated on several crops (canola, com, dry beans/peas, fallow, sorghum, soybeans, sugarcane, and sunflowers) as well as a decrease in pounds a.i. and percent crop treated, on peanuts only. The usage data for the remaining crops did not change with the addition of the most recent usage data in the 2015 SLUA.

For questions, comments and other usage information requests, please contact me at 703..:308-8140.

cc. Grant Rowland Pete Savoia

Dicamba Case (029801, 029802, 029803, 029806, 128931, 129043, and 128944) Screening Level Usage Analysis (SLUA) Date: June 24, 2015

What is a Screening Level Usage Analysis (SLUA)?

- Available estimates of pesticide usage data for a particular active ingredient that is used on agricultural crops in the United States.
- Pesticide usage data obtained from various sources. The data are then merged, averaged, and rounded so that the presented information is not proprietary, business confidential, or trade secret.

What does it contain?

- Pesticide usage data for a single active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information from U.S. states that produce 80% or more of a crop, in most cases, or less than 80%, in rare cases, depending on the scope of the survey and available resources.
- Annual percent of crop treated (average & maximum) for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

What assumptions can I make about the reported data?

- Average pounds of active ingredient applied Values are calculated by merging pesticide usage data sources together; averaging across all observations, then rounding. Note: If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)
- Average percent of crop treated Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. Note: If the estimated value is less than 2.5, then the value is labeled < 2.5. If the estimated value is less than 1, then the value is labeled < 1.
- Maximum percent of crop treated Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. Note: If the estimated value is less than 2.5, then the value is labeled <2.5.

What are the data-sources used?

- USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service) pesticide usage data from 2004 to 2013.
- Private pesticide market research -pesticide usage data from 2004 to 2013.
- California Department of Pesticide Regulation (DPR) Pesticide Use Reporting (PUR) data for 2004 to 2012.

What are the limitations to the data?

- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).
- Lack of reported usage data for the pesticide on a crop does not imply zero usage.
- Usage data on a particular site may be noted in data sources, but not quantified. In these instances, the site would not be reported in the SLUA.
- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.
- Some sites show some use, even though they are not on the label. This usage could be due to various factors, including, but not limited to Section 18 requests, existing stocks of the chemical, data collection errors, and experimental use permits (EUPs).

Date: June 24, 2015

Screening Level Estimates of Agricultural Uses of Dicamba Case (029801, 029802,

029803,029806,

128931, 129043, and 128944)*

Sorted

Alphabetically

Reporting

Years: 2004-

2013

		Annual Average	Percent Crop Treated	
	Crop	Lbs. A.I.	Avera2e	Maximum
1	Alfalfa+	2,000	<1	<2.5
2	Asparagus	< 500	5	10
3	Barley	20,000	5	10
4	Canola+	2,000	<2.5	10
5	Com	1,500,000	10	15
6	Cotton	200,000	5	15
7	Dry Beans/Peas+	3,000	<2.5	<2.5
8	Fallow	500,000	15	35
9	Oats	6,000	<2.5	<2.5
10	Pasture	600,000	<2.5	5
11	Peanuts+	1,000	<1	<2.5
12	Pecans+	1,000	<2.5	<2.5
13	Rice	3,000	<1	<2.5
14	Sorghum	200,000	15	25
15	Soybeans	100,000	<2.5	<2.5
16	Squash+	< 500	<2.5	<2.5
17	Sugarcane	40,000	20	25
18	Sunflowers+	9,000	5	10
19	Sweet Com	<500	<1	<2.5
20	Wheat	500,000	10	25

All numbers are rounded.

- <500: less than 500 pounds ofactive ingredients.
- <2.5: less than 2.5 percent of crop is treated.
- <1: less than 1 percent of crop is treated.

run.

SLUA data sources include:

USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service) Private Pesticide Market Research

These results reflect amalgamated data developed by the Agency and are releasable to the public.

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^{*} These PC codes (029804, 029805, 029807, 029808, 129042 and 408200) have no registered products.

^{+:} Crops not known to be listed on active end use product registrations or as Section 18 emergency exemptions when this report was





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PC Code: 128931 DP Barcodes: 404824

MEMORANDUM March 28, 2013

SUBJECT: Drinking Water Exposure Assessment for the Section 3 New Use of Dicamba

Diglycoamine Salt (DGA) and its Degradate 3,6-dichlorosalicylic acid (DCSA) on

Dicamba-tolerant Cotton

TO: Peter Salvia, Risk Assessor

> William Irwin, Toxicologist Michael Metzger, Branch Chief Risk Assessment Branch 5

Health Effects Division (7509P)

AND

Michael Walsh, Risk Manager Reviewer Kathryn Montague, Risk Manager (RM23)

Registration Division (7505P)

FROM: Reuben Baris, Environmental Scientist

Environmental Risk Branch 6

Environmental Fate and Effects Division (7507P)

THROUGH: Mark Corbin, Chief

Environmental Risk Branch 6

Environmental Fate and Effects Division (7507P)

This memo summarizes the estimated drinking water concentrations (EDWC) for dicamba diglycoamine salt (DGA) formulation and its degradate 3,6-dichlorosalicylic acid (DCSA) in surface water and groundwater in support of the human health dietary risk assessment for the Section 3 New Use on herbicide(dicamba)-tolerant cotton. Dicamba acid is formed by the dissociation of the following dicamba salts: dimethylamine, sodium, diglycolamine, isopropylamine, and potassium and as such this assessment presents all results as dicamba acid-equivalents (a.e.). All data for dicamba DGA salt were bridged from the acid supported by a dissociation study, field study, and TEP plant

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data indicating that the salt is not significantly different than the acid. Results from an acceptable dissociation rate study (MRID 43288001) showed that dicamba salts (sodium, potassium, dimethylamine, isopropylamine, and diglycolamine) reach essentially 100% dissociation within 75 seconds of the time of mixing with pure water. The EDWCs listed in Table 1 summarize the results in surface water and groundwater resulting from a single pre-emergent spray application and two overthe-top foliar applications (a total of 2.0 lbs a.e./A) to cotton. The soybean use was previously assessed by EFED in USEPA (2010; D378447). The EDWCs for soybean are summarized from USEPA (2010) (D378447) and also included in Table 1 as a courtesy to HED; the cotton EDWCs summarized in Table 1 are recommended for use in the HED human health dietary risk assessment for the dicamba use.

A Tier II screening-level drinking water exposure assessment was conducted for the proposed Section 3 New Use of the diglycolamine salt (DGA) formulation, expressed as dicamba acid-equivalent (ae), on dicamba-tolerant cotton. EDWCs in PRZM/EXAMS modeling resulting from use on cotton varied by the scenario used; acute 90th percentile 1-in-10 year concentrations ranged from 7.72 to 53.37 μg/L, the highest concentration reported from the Mississippi cotton scenario. Similarly for soybean, the highest concentration reported in USEPA, 2010 (D378447) was from the Mississippi soybean scenario; although slightly lower than the cotton EDWC. Chronic and 30-year average concentrations were also highest from the Mississippi scenarios for both soybean and cotton; results from additional scenarios are included in the Attachment to this memorandum. Tables 2 and 3 summarize the inputs used to conduct surface and groundwater modeling.

Surface water and groundwater monitoring data from the United States Geological Survey (USGS) NAWQA program1 were reviewed to provide some context to the EDWCs presented in Table 1. Note that analyses were only performed for the parent dicamba acid. Of the samples analyzed for dicamba, 275 (3.3%) out of 8,301 surface water samples had positive detections of dicamba; 15 (<1%) out of 6,434 samples in groundwater. The maximum concentration detected in surface water samples was 1.76 µg/L in the Rocky Creek at State Hwy 587 at Citrus Park, Hillsborough County, Florida. The maximum estimated concentration detected in the filter groundwater was 4.03 µg/L in urban area (SH:UR-18) in Shelby, Tennessee. The surface water concentrations ranged from 0.0094 to 1.76 µg/L, while groundwater concentrations ranged from 0.008 to 4.03 µg/L. Most of the data in NAWQA is non-targeted (i.e., study was not specifically designed to capture dicamba concentrations in high-use areas). Typically, sampling frequencies employed in monitoring studies are insufficient to capture and report actual peak exposure values. Coupled with the fact that these data are not necessarily temporally or spatially correlated with dicamba application times and/or areas limit the utility of these data in estimating drinking water concentrations for risk assessment. However, the maximum groundwater concentration reported is greater than the previously estimated concentration using SCIGROW, therefore EFED recommends the use PRZM-GW EDWC in the human health dietary risk assessment, reported in Table 1.

1 U.S. Geological Survey. 2001.

Table 1. EDWCs for drinking water exposure assessment based on the proposed dicamba DGA salt uses on dicamba-tolerant soybean and cotton*

Dicamba				
Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average (ug/L)
Surface Water**	MScottonSTD.txt	53.37	44.5	6.52
(PRZM/EXAMS)	MSsoybeanSTD.txt [†]	36.8 [†]	5.16 [†]	1.88 [†]
Groundwater		Peak (ug/L)	Post breakthrough average (ug/L)	30-year average (ug/L)
PRZM-GW (no pca applied)	WIsands.scn	329	187	158
SCIGROW		1.5E-3 [†]	w.w.	
DCSA				
Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average (ug/L)
Surface Water** (PRZM/EXAMS)	MScottonSTD.txt	2.97	2.59	0.63
Groundwater		Peak (ug/L)	Post breakthrough average (ug/L)	30-year average (ug/L)
PRZM-GW (no pca applied)	FLCitrus.scn	0.041	0.041	0.018
SCIGROW		5.9E-3		

^{*}Bold values indicate maximum value of the scenarios run. Recommended for use in dietary risk assessment.
**PCA corrected using all-agriculture PCA = 87%.

Table 2. Environmental fate input parameters for Dicamba used in PRZM/EXAMS and PRZM-GW for calculating surface water and groundwater EDWCs.

Parameter	Value	Source/Reference	Comments
Application rate	1.12 kg a.e./ha	Proposed Label	1.0 lb a.e./A pre-emergent (Apr. 16)
	0.56 kg a.e./ha		0.5 lb a.e./A (May 25, May 28)
	0.56 kg a.e./ha		
Interval between	3 days	Proposed Label	
applications			
Application Method	Ground spray	Proposed Label	
Molecular weight	221		
(g/mol)			
Solubility @ 25°C	6100		
(mg/L)			
Vapor Pressure (torr)	3.41x10 ⁻⁵		
Organic Carbon	13.4	MRID 42774101	Mean Koc. Also used as a groundwater
Partitioning Coefficient			input.
(K _{oc} , mL/g oc)			
Aerobic Soil Metabolism	18	MRID 43245207	Upper 90 th Percentile on the mean. Ground
half-life (days)			water input.

[†]Results from USEPA, 2010 (D378447).

[‡]100 year simulation, throughputs were <1.0 for 30 year simulation.

Aerobic Aquatic	72.9	MRID 43758509	3x a single half-life of 24.3 days was used
Metabolism half-life			(USEPA, 2009)
(days)			
Anaerobic aquatic metabolism half-life (days)	423	MRID 43245208	A single acceptable value (141 days). 3x a single value was used (USEPA, 2009)
Hydrolysis half-life (days, pH 7)	0	MRID 40547902	Stable. Also used in groundwater modeling.
Aqueous photolysis half- life (days)	105	MRID 42774102	

Table 3. Environmental fate input parameters for DCSA used in PRZM/EXAMS and PRZM-

GW for calculating surface water and groundwater EDWCs.

Parameter	Value	Source/Reference	Comments
Application rate	0.18 kg a.e./ha	Adjusted application rate for formation of	pre-emergent (Apr. 16); (May 25, May 28)
	0.09 kg a.e./ha 0.09 kg a.e./ha	degradate.	[(MW degradate)/(MW parent)] x Max %
	0.05 kg a.e./na	degradate.	formation x application rate = $207/221 \text{ x}$ 0.174 x 1.12 kg/ha = 0.18
Interval between applications	3 days	Proposed Label	V.174 X 1.12 Kg Ha V.10
Application Method	Ground spray	Proposed Label	
Molecular weight (g/mol)	207		
Solubility @ 25°C (mg/L)	112	MRID 43095301	
Vapor Pressure (torr)	3.41x10 ⁻⁵		For dicamba
Organic Carbon Partitioning Coefficient (K _{oc} , mL/g oc)	1208	MRID 43095301	Mean K _{oc.} Also used as a groundwater input.
Aerobic Soil Metabolism half-life (days)	24.6	MRID 43245207	Single value of 8.2 days, multiplied by 3 to account for potential variability in degradation in different soil types. Also used as a groundwater input.
Aerobic Aquatic Metabolism half-life (days)	49.2		No acceptable data, therefore per USEPA, 2009, assumed 2x the ASM t ½ (24.6 days).
Anaerobic aquatic metabolism half-life (days)	0	MRID 43245208	Stable.
Hydrolysis half-life (days, pH 7)	0	MRID 43245208	Stable. Also used in groundwater modeling.
Aqueous photolysis half- life (days)	105	MRID 42774102	No data for DCSA, therefore assumed value is equal to dicamba.

References:

USEPA. 2010. Drinking Water Assessment for Dicamba and its Degradate, 3,6-dichlorosalicylic acid (DCSA), for New Food Use on Dicamba-Tolerant Soybean. (Tolerance # 0F7725). Memorandum from I. Maher to C. Ollinger. DP Barcode: 378447. USEPA, Office of Pesticide Programs, Washington, DC 20460.

U.S. Geological Survey. 2001. National Water Information System (NWISWeb): U.S. Geological Survey database, accessed March 27, 2013, at http://water.usgs.gov/nawqa/data.

Attachment.

Table A-1. EDWCs for drinking water exposure assessment based on the proposed dicamba DGA salt uses on dicamba-tolerant soybean and cotton for all scenarios modeled*

	I	Dicamba		
Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average (ug/L)
SW**	CAcotton_wirrgSTD.txt	7.72	6.62	1.07
(PRZM/EXAMS)	MScottonSTD.txt	53.37	44.5	6.52
	NCcottonSTD.txt	32.14	27.32	4.24
	MSsoybeanSTD.txt [†]	36.8 [†]	5.16 [†]	1.88 [†]
Groundwater		Peak (ug/L)	Post breakthrough average (ug/L)	30-year average (ug/L)
PRZM-GW	GAcoastal	41.9	28.2	24.9
(no pca applied)	DELMARVA	192	121	117
	FLCitrus	238	161	155
	FLPotato	56.8	19.2	18.1
	NCcoastal	65.3	32.6	29.3
	WIsands	329	187	158
SCIGROW		1.5E-3 [†]	Not And	NA SAU
		DCSA		
Model	Use/Scenario	Acute (ug/L)	Chronic (ug/L)	30-year average (ug/L)
SW** (PRZM/EXAMS)	MScottonSTD.txt	2.97	2.59	0.63
Groundwater		Peak (ug/L)	Post breakthrough average (ug/L)	30-year average (ug/L)
PRZM-GW	GAcoastal [‡]	4.47E-5	3.93E-5	2.38E-5
(no pca applied)	DELMARVA	1.94E-4	1.65E-4	4.45E-5
	FLCitrus	0.041	0.041	0.018
	FLPotato [‡]	5.71E-11	3.67E-11	3.114E-11
	NCcoastal	7.31E-5	3.64E-5	2.59E-5
	WIsands [‡]	8.3E-4	7.66E-4	3.67E-4
SCIGROW		5.9E-3	na wa	NOW ONE

^{*}Bold values indicate maximum value of the scenarios run. Recommended for use in dietary risk assessment.

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^{**}PCA corrected using all-agriculture PCA = 87%.

[†]Results from USEPA, 2010 (D378447).

[‡]100 year simulation, throughputs were <1.0 for 30 year simulation.

Filename: E:\Dicamba Dietary\BAPMA Registration 2015\128931_Dicamba_Acute_Input File_Unrefined_BAPMA Action_Sept 2015_Food and Drinking Water_.TXT Chemical: Dicamba (029801, 029802, 029806, 128931, 128944, and 129043) RfD(Chronic): .04 mg/kg bw/day NOEL(Chronic): 4 mg/kg bw/day RfD(Acute): .29 mg/kg bw/day NOEL(Acute): 29 mg/kg bw/day Date created/last modified: 10-15-2015/11:33:52 Program

Program ver. 3.16, 03-08-d

Comment: Ground Water Parent and Metabolite Residues Combined for all Crops; No Acute Endpt for Females 13-49: Unrefined Tolerance Level Assessment for Acute BAPMA Action Sept 2015

	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Fa #1	ctors #2	Comment
0600347000 6	ì	Soybean, seed	10.000000	1.000	1.000	
0600349000 6		Soybean, soy milk	10.000000	1.000	1.000	
0600349001 6		Soybean, soy milk-babyfood or in	10.000000	1.000	1.000	
0600350000 6		Soybean, oil	10.000000	1.000	1.000	
0600350001 6		Soybean, oil-babyfood	10.000000	1.000	1.000	
0603348000 6		Soybean, flour	10.000000	1.000	1.000	
0603348001 6		Soybean, flour-babyfood	10.000000	1.000	1.000	
1500025000 1		Barley, pearled barley	6.000000	1.000	1.000	
1500025001 1	. 5	Barley, pearled barley-babyfood	6.000000	1.000	1.000	
1500026000 1		Barley, flour	6.000000	1.000	1.000	
1500026001 1	.5	Barley, flour-babyfood	6.000000	1.000	1.000	
1500027000 1	. 5	Barley, bran	6.000000	1.000	1.000	
1500120000 1	. 5	Corn, field, flour	0.100000	1.000	1.000	
1500120001 1	. 5	Corn, field, flour-babyfood	0.100000	1.000	1.000	
1500121000 1	. 5	Corn, field, meal	0.100000	1.000	1.000	
1500121001 1	. 5	Corn, field, meal-babyfood	0.100000	1.000	1.000	
1500122000 1		Corn, field, bran	0.100000	1.000	1.000	
1500123000 1		Corn, field, starch	0.100000	1.000	1.000	
1500123001 1		Corn, field, starch-babyfood	0.100000	1.000	1.000	
1500124000 1		Corn, field, syrup	0.100000	1.500	1.000	
1500124001 1		Corn, field, syrup-babyfood	0.100000	1.500	1.000	
1500125000 1		Corn, field, oil	0.100000	1.000	1.000	
1500125001 1		Corn, field, oil-babyfood	0.100000	1.000	1.000	
1500126000 1		Corn, pop	0.100000	1.000	1.000	
1500127000 1		Corn, sweet	0.040000	1.000	1.000	
1500127001 1		Corn, sweet-babyfood	0.040000	1.000	1.000	
1500226000 1		Millet, grain	2.000000	1.000	1.000	
1500231000 1		Oat, bran	2.000000	1.000	1.000	
1500232000 1		Oat, flour	2.000000	1.000	1.000	
1500232001 1		Oat, flour-babyfood	2.000000	1.000	1.000	
1500233000 1 1500233001 1		Oat, groats/rolled oats	2.000000	1.000	1.000	
1500233001 1		Oat, groats/rolled oats-babyfood Rye, grain	2.000000	1.000	1.000	
1500328000 1		Rye, flour	2.000000	1.000	1.000	
1500323000 1		Sorghum, grain	4.000000	1.000	1.000	
1500344000 1		Sorghum, syrup	4.000000	1.000	1.000	
1500401000 1		Wheat, grain	2.000000	1.000	1.000	
1500401001 1		Wheat, grain-babyfood	2.000000	1.000	1.000	
1500402000 1		Wheat, flour	2.000000	1.000	1.000	
1500402001 1		Wheat, flour-babyfood	2.000000	1.000	1.000	
1500403000 1		Wheat, germ	2.000000	1.000	1.000	
1500404000 1		Wheat, bran	2.000000	1.000	1.000	
2003128000 2	0C	Cottonseed, oil	3.000000	1.000	1.000	
2003128001 2	0C	Cottonseed, oil-babyfood	3.000000	1.000	1.000	
3100044000 3		Beef, meat	0.250000	1.000	1.000	
3100044001 3	31	Beef, meat-babyfood	0.250000	1.000	1.000	
3100045000 3	31	Beef, meat, dried	0.250000	1.920	1.000	
3100046000 3	31	Beef, meat byproducts	3.000000	1.000	1.000	
3100046001 3		Beef, meat byproducts-babyfood	3.000000	1.000	1.000	
3100047000 3		Beef, fat	0.300000	1.000	1.000	
3100047001 3		Beef, fat-babyfood	0.300000	1.000	1.000	
3100048000 3		Beef, kidney	25.000000	1.000	1.000	
3100049000 3		Beef, liver	3.000000	1.000	1.000	
3100049001 3		Beef, liver-babyfood	3.000000	1.000	1.000	
3200169000 3		Goat, meat	0.250000	1.000	1.000	
3200170000 3	32	Goat, meat byproducts	3.000000	1.000	1.000	

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3200171000 32 3200172000 32	Goat, fat Goat, kidney	0.300000 25.000000	1.000	1.000
3200173000 32	Goat, liver	3.000000	1.000	1.000
3300189000 33	Horse, meat	0.250000	1.000	1.000
3400290000 34	Pork, meat	0.250000	1.000	1.000
3400290001 34	Pork, meat-babyfood	0.250000	1.000	1.000
3400291000 34	Pork, skin	3.000000	1.000	1.000
3400292000 34	Pork, meat byproducts	3.000000	1.000	1.000
3400292001 34	Pork, meat byproducts-babyfood	3.000000	1.000	1.000
3400293000 34	Pork, fat	0.300000	1.000	1.000
3400293001 34	Pork, fat-babyfood	0.300000	1.000	1.000
3400294000 34	Pork, kidney	25.000000	1.000	1.000
3400295000 34	Pork, liver	3.000000	1.000	1.000
3500339000 35	Sheep, meat	0.250000	1.000	1.000
3500339001 35	Sheep, meat-babyfood	0.250000	1.000	1.000
3500340000 35	Sheep, meat byproducts	3.000000	1.000	1.000
3500341000 35	Sheep, fat	0.300000	1.000	1.000
3500341001 35	Sheep, fat-babyfood	0.300000	1.000	1.000
3500342000 35	Sheep, kidney	25.000000	1.000	1.000
3500343000 35	Sheep, liver	3.000000	1.000	1.000
3600222000 36	Milk, fat	0.200000	1.000	1.000
3600222001 36	Milk, fat-baby food/infant formu	0.200000	1.000	1.000
3600223000 36	Milk, nonfat solids	0.200000	1.000	1.000
3600223001 36	Milk, nonfat solids-baby food/in	0.200000	1.000	1.000
3600224000 36	Milk, water	0.200000	1.000	1.000
3600224001 36	Milk, water-babyfood/infant form	0.200000	1.000	1.000
3600225001 36	Milk, sugar (lactose)-baby food/	0.200000	1.000	1.000
8601000000 86A	Water, direct, all sources	0.329041	1.000	1.000
8602000000 86B	Water, indirect, all sources	0.329041	1.000	1.000
9500019000 O	Asparagus	4.000000	1.000	1.000
9500362000 O	Sugarcane, sugar	0.300000	1.000	1.000
9500362001 0	Sugarcane, sugar-babyfood	0.300000	1.000	1.000
9500363000 O	Sugarcane, molasses	5.000000	1.000	1.000
9500363001 0	Sugarcane, molasses-babyfood	5.000000	1.000	1.000
9500373500 O	Teff, flour	6.000000	1.000	1.000

US EPA Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for DICAMBA (029801, 029802, 029806, 128931, 128944, AND 129043)
NHANES 2003-2008 2-Day

Residue file: 128931_Dicamba_Acute_Input File_Unrefined_BAPMA Action_Sept 2015_Food and Drinking Water.R08

Adjustment factor #2 used.

Analysis Date: 10-15-2015/11:41:36 Residue file dated: 10-15-2015/11:33:52

NOEL (Acute) = 29.000000 mg/kg body-wt/day

RAC/FF intake summed over 24 hours

Run Comment: "Ground Water Parent and Metabolite Residues Combined for all Crops; No Acute Endpt for Females 13-49: Unrefined Tolerance Level Assessment for Acute_BAPMA Action_Sept 2015 "

Summary calculations--per capita:

95th	Percentil	e	99th	Percentil	Le	99.9th	Percenti	le
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Total US Po	 bulation:							
0.042760	-	678	0.070910	24.45	408	0.176225	60.77	164
All Infants	:							
0.088733	30.60	326	0.123532	42.60	234	0.430231	148.36	67
Children 1-	2:							
0.075295	25.96	385	0.185363	63.92	156	0.874135	301.43	33
Children 3-	5:							
	22.69	440	0.147118	50.73	197	0.466474	160.85	62
Children 6-								
0.047142	16.26	615	0.073376	25.30	395	0.287964	99.30	100
Youth 13-19								
	11.09	901	0.050366	17.37	575	0.122480	42.23	236
Adults 20-4								
0.035172	12.13	824	0.058497	20.17	495	0.107617	37.11	269
Adults 50-9								
0.029776	10.27	973	0.051032	17.60	568	0.138606	47.80	209
Female 13-4								
0.032628	11.25	888	0.055286	19.06	524	0.112472	38.78	257

Filename: E:\Dicamba Dietary\BAPMA Registration 2015\128931_Dicamba_Chronic_Input File_Refined with Avg Crop Residues_BAPMA Action_Sept 2015_Food and Drinking Water.R08
Chemical: Dicamba (029801, 029802, 029806, 128931, 128944, and 129043)
RfD(Chronic): .04 mg/kg bw/day NOEL(Chronic): 4 mg/kg bw/day
RfD(Acute): .29 mg/kg bw/day NOEL(Acute): 29 mg/kg bw/day
Date created/last modified: 09-24-2015/13:25:16 Program ver. 3.16, 03-08-d
Comment: Ground Water Parent and Metabolite Residues Combined for all Crops; No Acute Endpt
for Females 13-49; Refined Assessment Using Average Residues, %CT Data & 100%CT for Avg Crop Redisues & Livestock Tolerance Values_BAPMA Action_September 2015

EPA	Crop		Def Res	Adj Fa	ctors	Comment
Code	Grp	Commodity Name	(ppm)	#1	#2	
0600247000			1 100000	1 000		
0600347000 0600349000		Soybean, seed Soybean, soy milk	1.100000 1.100000	1.000	1.000	
0600349000		Soybean, soy milk-babyfood or in	1.100000	1.000	1.000	
0600349001		Soybean, oil	1.100000	1.000	1.000	
0600350001		Soybean, oil-babyfood	1.100000	1.000	1.000	
0603348000		Soybean, flour	1.100000	1.000	1.000	
0603348001		Soybean, flour-babyfood	1.100000	1.000	1.000	
1500025000		Barley, pearled barley	1.300000	1.000	0.050	
1500025000		Barley, pearled barley-babyfood	1.300000	1.000	0.050	
1500026000		Barley, flour	1.300000	1.000	0.050	
1500026001		Barley, flour-babyfood	1.300000	1.000	0.050	
1500027000		Barley, bran	1.300000	1.000	0.050	
1500120000		Corn, field, flour	0.010000	1.000	0.100	
1500120001		Corn, field, flour-babyfood	0.010000	1.000	0.100	
1500121000		Corn, field, meal	0.010000	1.000	0.100	
1500121001		Corn, field, meal-babyfood	0.010000	1.000	0.100	
1500122000		Corn, field, bran	0.010000	1.000	0.100	
1500123000		Corn, field, starch	0.010000	1.000	0.100	
1500123001		Corn, field, starch-babyfood	0.010000	1.000	0.100	
1500124000		Corn, field, syrup	0.010000	1.500	0.100	
1500124001		Corn, field, syrup-babyfood	0.010000	1.500	0.100	
1500125000		Corn, field, oil	0.010000	1.000	0.100	
1500125001		Corn, field, oil-babyfood	0.010000	1.000	0.100	
1500126000		Corn, pop	0.010000	1.000	0.100	
1500127000	15	Corn, sweet	0.020000	1.000	0.010	
1500127001	15	Corn, sweet-babyfood	0.020000	1.000	0.010	
1500226000	15	Millet, grain	0.400000	1.000	1.000	Transl
	Ful.	l comment: Translated from wheat				
1500231000	15	Oat, bran	0.400000	1.000	0.025	Transl
	Ful.	l comment: Translated from wheat				
1500232000	15	Oat, flour	0.400000	1.000	0.025	Transl
	Ful.	l comment: Translated from wheat				
1500232001		Oat, flour-babyfood	0.400000	1.000	0.025	Transl
	Ful.	l comment: Translated from wheat				
1500233000	15	Oat, groats/rolled oats	0.400000	1.000	0.025	Transl
	Ful.	l comment: Translated from wheat				
1500233001		Oat, groats/rolled oats-babyfood	0.400000	1.000	0.025	Transl
		l comment: Translated from wheat				
1500328000		Rye, grain	0.400000	1.000	1.000	Transl
		l comment: Translated from wheat				
1500329000		Rye, flour	0.400000	1.000	1.000	Transl
		l comment: Translated from wheat				
1500344000		Sorghum, grain	1.500000	1.000	0.150	
1500345000		Sorghum, syrup	1.500000	1.000	0.150	
1500401000		Wheat, grain	0.400000	1.000	0.100	
1500401001		Wheat, grain-babyfood	0.400000	1.000	0.100	
1500402000		Wheat, flour	0.400000	1.000	0.100	
1500402001		Wheat, flour-babyfood	0.400000	1.000	0.100	
1500403000		Wheat, germ	0.400000	1.000	0.100	
1500404000		Wheat, bran	0.400000	1.000	0.100	
2003128000		Cottonseed, oil	0.500000	1.000	1.000	
2003128001		Cottonseed, oil-babyfood Beef, meat	0.500000	1.000	1.000	
3100044000		Beef, meat-babyfood	0.250000 0.250000	1.000	1.000	
3100044001	2.1	peer, mear-papyrood	0.250000	1.000	1.000	

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3100045000 31
                Beef, meat, dried
                                                       0.250000
                                                                 1.920 1.000
                Beef, meat byproducts
3100046000 31
                                                      3.000000 1.000 1.000
3100046001 31
                 Beef, meat byproducts-babyfood
                                                       3.000000
                                                                  1.000 1.000
3100047000 31
                Beef, fat
                                                      0.300000
                                                                  1.000 1.000
                Beef, fat-babyfood
Beef, kidney
Beef, liver
3100047001 31
                                                      0.300000
                                                                  1.000 1.000
3100048000 31
3100049000 31
                                                  3.000000
3.000000
0.25000
                                                     25.000000
                                                                  1.000 1.000
                                                                  1.000 1.000
3100049001 31
                 Beef, liver-babyfood
                                                                  1.000 1.000
                Goat, meat
Goat, meat byproducts
                                                     0.250000
3.000000
                                                                  1.000 1.000
1.000 1.000
3200169000 32
3200170000 32
3200171000 32
                                                     0.300000
                                                                  1.000 1.000
                 Goat, fat
                Goat, kidney
Goat, liver
3200172000 32
                                                                  1.000 1.000
1.000 1.000
                                                   25.000000
                                                   3.000000
0.250000
3200173000 32
                                                                  1.000 1.000
3300189000 33
                 Horse, meat
                                                    0.250000
3400290000 34
                                                                  1.000 1.000
                Pork, meat
3400290001 34
                                                    0.250000
3.000000
                                                      0.250000
                                                                  1.000 1.000
                 Pork, meat-babyfood
                 Pork, skin
3400291000 34
                                                                  1.000 1.000
                Pork, meat byproducts
                Pork, meat byproducts 3.000000
Pork, meat byproducts-babyfood 3.000000
Pork, fat 0.300000
3400292000 34
                                                                  1.000 1.000
3400292001 34
                                                                  1.000 1.000
                                                                  1.000 1.000
3400293000 34
                Pork, fat-babyfood
Pork, kidney
Pork, liver
3400293001 34
                                                      0.300000
                                                                  1.000 1.000
                                                   25.000000
3400294000 34
                                                                  1.000 1.000
                                                                  1.000 1.000
3400295000 34
                                                      3.000000
                                                   0.250000
3500339000 35
                 Sheep, meat
                                                                  1.000 1.000
                 Sheep, meat-babyfood
                                                0.250000
3.000000
0.300000
                                                                  1.000 1.000
1.000 1.000
3500339001 35
3500340000 35
                 Sheep, meat byproducts
3500341000 35
                 Sheep, fat
                                                                  1.000 1.000
                 Sheep, fat-babyfood
Sheep, kidney
                                                      0.300000
                                                                  1.000 1.000
3500341001 35
                                                   25.000000
3500342000 35
                                                                  1.000 1.000
3500343000 35
                 Sheep, liver
                                                     3.000000
                                                                  1.000 1.000
                Milk, fat 0.200000
Milk, fat-baby food/infant formu 0.200000
3600222000 36
                                                                  1.000 1.000
                                                      0.200000
3600222001 36
                                                                  1.000 1.000
3600223000 36
                                                                  1.000 1.000
                Milk, nonfat solids
                                                      0.200000
3600223001 36
                Milk, nonfat solids-baby food/in 0.200000
                                                                  1.000 1.000
                Milk, water 0.200000
Milk, water-babyfood/infant form 0.200000
3600224000 36
                                                                  1.000 1.000
                                                                  1.000 1.000
3600224001 36
3600225001 36
                Milk, sugar (lactose)-baby food/ 0.200000
                                                                  1.000 1.000
8601000000 86A Water, direct, all sources
8602000000 86B Water, indirect, all sources
                                                 0.187041
0.187041
                                                                  1.000 1.000
1.000 1.000
                                                     1.000000
                                                                 1.000 0.050
9500019000 O
                 Asparagus
9500362000 O
                                                      0.140000
                                                                  1.000 0.200
                 Sugarcane, sugar
9500362001 O
                 Sugarcane, sugar-babyfood
                                                      0.140000
                                                                  1.000 0.200
9500363000 O
                 Sugarcane, molasses
                                                      3.400000
                                                                  1.000 0.200
9500363001 0
                 Sugarcane, molasses-babyfood
                                                      3.400000
                                                                  1.000 0.200
9500373500 O
                                                       1.300000
                                                                  1.000 1.000 Transl
                 Teff, flour
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Full comment: Translated from Barley

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Adults 50-99

Female 13-49

ATTACHMENT 6

US EPA Ver. 3.16, 03-08-d
DEEM-FCID Chronic analysis for DICAMBA (029801, 029802, 029806, 128931, 128944, AND 129043)
NHANES 2003-2008 2-day

Residue file name: E:\Dicamba Dietary\BAPMA Registration 2015\128931_Dicamba_Chronic_Input File_Refined with Avg Crop Residues_BAPMA Action_Sept 2015_Food and Drinking Water.R08 Adjustment factor #2 used.

Analysis Date 10-15-2015/11:43:17 Residue file dated: 10-15-2015/11:36:52 Reference dose (RfD, Chronic) = .04 mg/kg bw/day

COMMENT 1: Ground Water Parent and Metabolite Residues Combined for all Crops; No Acute Endpt for Females 13-49; Refined Assessment Using Average Residues, %CT Data & 100%CT for Avg Crop Redisues & Livestock Tolerance Values_BAPMA Action_September 2015

Total Exposure

13.3%

13.7%

Total exposure by population subgroup

Population Subgroup	mg/kg body wt/day	Percent of Rfd		
Total US Population	0.006319	15.8%		
Hispanic	0.006592	16.5%		
Non-Hisp-White	0.006373	15.9%		
Non-Hisp-Black	0.005361	13.4%		
Non-Hisp-Other	0.007169	17.9%		
Nursing Infants	0.004789	12.0%		
Non-Nursing Infants	0.018149	45.4%		
Female 13+ PREG	0.005659	14.1%		
Children 1-6	0.013494	33.7%		
Children 7-12	0.007114	17.8%		
Male 13-19	0.005016	12.5%		
Female 13-19/NP	0.004863	12.2%		
Male 20+	0.005297	13.2%		
Female 20+/NP	0.005576	13.9%		
Seniors 55+	0.005264	13.2%		
All Infants	0.014024	35.1%		
Female 13-50	0.005460	13.6%		
Children 1-2	0.016988	42.5%		
Children 3-5	0.011947	29.9%		
Children 6-12	0.007618	19.0%		
Youth 13-19	0.004936	12.3%		
Adults 20-49	0.005526	13.8%		

0.005340

0.005465

Crop group

Food Foodform

Total for crop group

Total for crop group

Crop Group = (86B) Indirect Water

Water, indirect, all sources (8602000000): FoodForm N/S

ATTACHMENT 7

Ver. 3.16, 03-08-d DEEM-FCID Chronic analysis for DICAMBA (029801, 029802, 029806, 128931, 128944, AND 129043) NHANES 2003-2008 2-day

Residue file name: E:\Dicamba Dietary\BAPMA Registration 2015\128931 Dicamba Chronic Input File Refined with Avg Crop Residues BAPMA Action Sept 2015 Food and Drinking Water.R08 Adjustment factor #2 used.

Analysis Date 10-15-2015/11:43:22 Residue file dated: 10-15-2015/11:36:52

Reference dose (RfD, Chronic) = .04 mg/kg bw/day

COMMENT 1: Ground Water Parent and Metabolite Residues Combined for all Crops; No Acute Endpt for Females 13-49; Refined Assessment Using Average Residues, %CT Data & 100%CT for Avg Crop Redisues & Livestock Tolerance Values_BAPMA Action_September 2015

-----Exposure Analysis-----

Critical Commodity Contribution Analysis for Children 1-2

Total Exposure = .0169885 mg/kg bw/day

Crop groups with total exposure contribution > 5% Foods/Foodforms with exposure contribution > 3%

mg/kg % of Total Percent body wt/day Exposure of RfD Crop Group = (36) Milk Milk, nonfat solids (3600223000): FoodForm N/S 0.0008510 5.01% 2.13% Milk, water (3600224000): FoodForm N/S 0.0072998 42.97% 18.25% Total for crop group 0.0084982 50.02% 21.25% Crop Group = (86) Water Water, direct, all sources (8601000000): FoodForm N/S 0.0036343 21.39% 9.09% Water, indirect, all sources (8602000000): 0.0020154 11.86% 5.04% FoodForm N/S Total for crop group 0.0056497 33.26% Crop Group = (86A) Direct Water Water, direct, all sources (8601000000): FoodForm N/S 0.0036343 21.39% 9.09%

FoodForm N/S 0.0020154 11.86% 5.04%

Total for crop groups listed above: 0.0141479 83.28% 35.4%

0.0036343 21.39%

11.86%

5.04%

0.0020154